LABORATORY ACCREDITATION BUREAU

Quality System Manual

(Revision 18 06/21/11)

1. ACCESS TO ACCREDITATION

It is the policy of Laboratory Accreditation Bureau (L-A-B) to accept applications for accreditation from any laboratory regardless of size and to administer the program in a non-discriminatory manner. Access to accreditation is not dependent upon membership in any association or group. L-A-B provides all clients with the same contractual agreement, Form R20.4, Laboratory Accreditation Agreement. L-A-B reserves the right to deny an application based on legal status of an organization and/or Federal, State, Local authorities legally binding mandate.

2. ORGANIZATION OF LABORATORY ACCREDITATION BUREAU (L-A-B)

L-A-B is a Limited Liability Company, incorporated in the state of Michigan. L-A-B is organized in a manner to assure that personnel have the necessary education, training, technical knowledge and experience for handling the type, range and volume of work performed. The structure of the organization is defined in the organization chart (See Form 311). All staff sign Form R20.10 Code of Conduct and Form R20.29 Conflict of Interest. Technical Advisory Group Members and Expert Committee Members sign a Code of conduct and Conflict of Interest. See committee charters for further detail of their activities.

L-A-B utilizes the website, www.l-a-b.com, in order to supply documents, make records public, and give general information about the accreditation process and its fees. Information on related bodies, authority of operations, and a description of its rights and duties are also provided on the website in the form of our objectives. These concepts are updated, as needed, and regularly available on the website.

The following personnel and committees are available to provide guidance and develop policies and procedures. In addition, the Technical Advisory Group provides the necessary technical expertise to accredit laboratories. The TAG Charters define the appointment methods along with the responsibilities of the TAG.

A. DISPUTE AND APPEALS REVIEW COMMITTEE (EXECUTIVE TAG)

Purpose: Impartial resolution of disputes and appeals.
Appointed by: Managing Director with input from appellant.
Reports to: Managing Director
Membership: Individuals without conflict of interest who understand the requirements of accreditation and assessment principles. The Executive TAG is the standing Dispute and Appeals Review Committee. Upon contractual agreement other stakeholders in the laboratory accreditation process may provide dispute and/or appeal resolution recommendations.

B. TECHNICAL ADVISORY GROUP (TAG)

Purpose: Give advice to L-A-B on the technical and policy matters relating to the operation of its accreditation system. Chosen Members may give recommendations on Technical reviews to provide the necessary technical review for accreditation and scopes prior to publication.
Appointed by: Managing Director and Technical Program Managers
Reports to: Managing Director
Membership: Individuals from various sectors and roles in laboratories and industry who have interest in and understand the requirements of accreditation and assessment principles.

C. TAG SECTOR SPECIFIC COMMITTEES

Purpose: Expert determination of ISO/IEC 17025 interpretations when required for specific types of tests or calibrations. Chosen Members to give recommendations on technical reviews and scopes prior to publication
Appointed by: Managing Director and Program Managers
Reports to: Managing Director
Membership: One or more respected, impartial and technically competent individuals qualified to address the scope and technical issues presented by ISO/IEC 17025 and the specific types of tests or calibrations. A member of the TAG typically chairs the committee and members may be drawn for the TAG or industry experts.

D. STAFF

A job description is available for all L-A-B Staff and assessors. The job description defines the position's operational and functional duties and services as it pertains to quality. Staff and assessors have resumes on file that describe their qualifications, education and experience. All staff shall sign Form R20.10 Code of Conduct and Form R20.29 Conflict of Interest.

E. MANAGEMENT

The accreditation body identifies the top management having overall authority and responsibility for each of the following:

a) Development of policies relating to the operation of L-A-B
b) Document of policies and objectives, along with the supervision of the implementation of those policies and procedures
c) Supervision of the finances of L-A-B
d) Decisions on accreditation after soliciting the appropriate technical input
e) Contractual arrangements
f) Delegation of authority to committees or individuals, as required, to undertake defined activities on behalf of top management.

Management will document, implement, maintain, and formulate policies wherever applicable to the International Standards. Management will assure that a sufficient number of competent personnel (internal, external, temporary, or permanent, full time or part time) have the education, training, technical knowledge, skills and experience necessary for handling the accreditation of laboratories. Management will assure that duties are defined for all personnel including their responsibility to confidentiality and ethics.

3. QUALITY SYSTEM

The Quality Manager has the responsibility for implementing the Laboratory Accreditation Bureau's quality system. The Quality Manager maintains the quality documentation, and assures that it remains up-to-date. The Quality Manager reports to the Managing Director

A. QUALITY POLICY

Laboratory Accreditation Bureau attests to the competence of laboratories. L-A-B facilitates trade by promoting global acceptance of accredited laboratories. The confidence of L-A-B's accreditation originates in our mutual recognition and peer evaluation. L-A-B provides all accredited laboratories

confidence in accreditation and the ability to accept test reports and calibration certificates nationally and internationally. Service, communication and integrity back the attestation and the ability to gain confidence in L-A-B's Accreditation Programs.

B. INTERNAL AUDIT SEE SOP 103 "INTERNAL AUDITS & QUALITY SYSTEM REVIEW"

The Quality System is audited normally out least once per year. The audit will verify that L-A-B complies with the requirements of this quality system and ISO/IEC 17011. The audit will examine all aspects of L-A-B's Quality System as defined in this manual, including organization of quality program, corrective actions, record control, personnel training, client complaints, and all details set forth in this manual.

The accreditation body ensures that:

a) Internal audits are conducted by qualified personnel knowledgeable in accreditation, auditing and the requirements of this International Standard
b) Internal audits are conducted by personnel different from those who perform the activity to be audited where possible
c) Personnel responsible for the area audited are informed of the outcome of the audit
d) Actions are taken in a timely and appropriate manner
e) Any opportunities for improvement are identified.

The Quality Manager will review and respond to all audit noncompliance's, utilizing the Corrective Action Procedure SOP 104. The Quality Manager or designee is responsible for verifying implementation and approving corrective actions required by the audit.

Frequency of audits may increase for the following reasons; unsatisfactory performance during the audit, corrective action responses, complaints, or any other action that may cast doubt on the activities of L-A-B.

C. MANAGEMENT REVIEW SEE SOP 103 "INTERNAL AUDITS & QUALITY SYSTEM REVIEW"

Normally a management review meeting will be held once per year to determine if L-A-B's Quality System remains effective for the type, range and volume of work performed. Additionally the requirements of ISO/IEC 17011 will be evaluated with established procedures during the internal audit and results reported appropriately. Corrective actions both internal and external, and client complaints and appeals will be reviewed. Trends in non-compliances will be considered if relevant. Consideration is also given to the outcome of recent internal and external audits. If applicable, attention is given to feedback from peer reviews and from interested parties involved. Follow-up actions from earlier management reviews and fulfillment of objectives are considered. Other possible areas of quality system review are:

a) Participation in international activities
b) New areas of accreditation
c) Trends in nonconformities
d) Status of preventive and corrective actions
e) Any changes that could affect the management system

Attention is given to other relevant quality aspects such as resources, training and staff qualifications.

The improvement of services and accreditation process in conformity with the relevant standards and expectation and feedback of interested parties are assessed upon completion of the review. The

review process must convey the need for resources and defining or redefining of policies, goals and objectives. The review, and actions taken as a result, will be formally reported to the Quality Manager for consideration and action. The Quality Manager is responsible for actions that improve the management system and its processes. The Quality Manager and appropriate personnel are responsible for ensuring that the approved actions are implemented within an appropriate time frame. The improvements will include the management system, improvement of the accreditation system and service, defining or redefining policies and/or objectives. Additional recourses may be needed to assist in the improvement activity.

D. CORRECTIVE ACTIONS SEE SOP 104

Whenever discrepancies are detected, all actions and evaluations will be recorded and implemented in a timely manner. The following steps are taken to assure that they are resolved to the satisfaction of all parties involved.

A. Identification of discrepancies

Situations needing corrective action may be identified through audits, client complaints, or other circumstances that indicate a departure from documented policies and procedures.

B. Identification of Root Cause

Detailed information pertaining to the cause must be stated so an adequate solution can be implemented. Root cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include requirements, methods and procedures, or staff skills and training.

C. Interim Action

Detailed information on what steps were taken to correct the immediate problem.

D. Corrective Action

Actions taken to correct the discrepancy will be irreversible, whenever possible. Complete details are documented describing what actions were taken to eliminate the discrepancy. The effective of the corrective actions taken will be reviewed.

E. Preventive Actions

L-A-B has established procedures to identify opportunities for improvements and to take preventive actions to eliminate the causes of potential nonconformities. The preventive actions taken are appropriate to the impact of the potential problems and give details on actions to be taken to assure the discrepancy does not recur. The procedures for preventive actions will define requirements for

a) Identifying potential nonconformities and their causes
b) Determining and implementing the preventive actions needed
c) Recording results of actions taken, and
d) Reviewing the effectiveness of the preventive actions taken

E. COMPLAINTS SEE SOP 203

L-A-B views complaints as an opportunity to improve. Upon receipt of a complaint, L-A-B will review the validity of the complaint. Where appropriate L-A-B will ensure that the complaint has been addressed by the laboratory first. From here, L-A-B will take the necessary actions and assess their effectiveness to solve the issue. Complaints that cannot be resolved in the course of staff's normal routine are forwarded to the Quality Manager. The Quality Manager establishes the course of action required to resolve the complaint. All complaints and appropriate actions will be recorded. L-A-B will respond to the complainant where the actions may include but are not limited to:

1) Issuing a corrective action in accordance with SOP 104
2) Audit the activity involved in accordance with SOP 103.

F. DOCUMENT CONTROL SOP 102

The accreditation body will establish procedures to control all documents (internal and external) that relate to its accreditation activities and have them readily available to all personnel, subcontractors, experts, assessors, and laboratories at any point in the accreditation process. Documents must remain legible and readily identifiable. The controls needed to prevent the unintended use of obsolete documents, to apply suitable identification to them if they are retained for any purpose, and to safeguard where relevant, the confidentiality of documents are defined by L-A-B (see SOP 102).

All manuals and procedures developed by L-A-B are controlled. Each procedure is developed using L-A-B SOP 101 "Procedure for Standard Operating Procedures." Each procedure is uniquely identified, and contains the following information:

1. Subject
2. Unique identification number
3. Who is responsible for the procedure
4. Revision number
5. Revision date
6. Page ___of ____
7. Policy / Policy reference
8. Purpose and Scope
9. Responsibility
10. Action/Method to Achieve the System Element Requirement
11. Documentation/References
12. Records generated using the procedure

Manuals will be uniquely identified and include the following identifying information:

1. Unique identification Title or Number
2. Person responsible for the manual
3. Revision number and date
4. Page____of _____

As a minimum the following documents are controlled:

1. Quality System Manual
2. Standard Operating Procedures (SOP)
3. Forms as identified in SOPs, and other documents
4. Guidance documents
5. Policies
6. Affiliate Handbook
7. Client Instruction Manual

G. IMPARTIALITY

The accreditation body will be organized, structured, and operated so as to safeguard the objectivity and impartiality of its activities. Conformity assessment services and consultancy cannot be provided by L-A-B or its employees in order to uphold impartiality. Each decision on accreditation is taken by competent person(s) or committee(s) different from those who carried out the assessment. L-A-B ensures that the activities of its related bodies do not compromise the confidentiality, objectivity and impartiality of its accreditations.

A related body may offer consultancy of present conformity assessment services provided they have the following:

1. Different top management then mentioned in section 2, part F
2. No overlap between the decision making processes, and no interference in the decision making of accreditation
3. Distinctly different names, logos, and symbols.

4. AUTHORITY

Laboratory Accreditation Bureau was formed to provide accreditation services to calibration and testing laboratories. L-A-B is authorized by specifiers and certain regulators to provide accreditation to ISO/IEC 17025 for the laboratories that provide services to them and their suppliers. L-A-B is recognized by the National Cooperation for Laboratory Accreditation, NACLA, with a "Scope of Recognition" (www.nacla.net), the Asia Pacific Laboratory Accreditation Cooperation, APLAC, (www.aplac.org) and the International Laboratory Accreditation Cooperation, ILAC (www.ilac.org).

5. LABORATORY ASSESSORS

L-A-B has access to a sufficient number of assessors, including lead assessors, and experts to cover all of its activities. The duties, responsibilities, and authorities are made clear to each person.

A. ASSESSOR QUALIFICATIONS

See SOP 105 "Assessor Qualifications" for details of assessor qualifications. Laboratory assessors must have direct laboratory experience in the fields of testing and calibration for which they will be performing assessments. They are trained in the use of the methods and documents used for assessments. L-A-B has an extensive training program that verifies an assessor's technical qualification. Assessors must be able to communicate effectively both orally and in writing while maintaining a suitable and effective personality. Assessors will have relevant knowledge of different assessment methods and of legal regulations in their field of expertise. Records of assessor's qualifications and training are kept on file.

Assessors will be free from pressures and conflicts of interest on each assessment. All assessors must sign Conflict of Interest and Code of Conduct Form. Assessors must not have

offered consultancy to laboratories in the past two years, which might compromise their impartiality.

Assessors are provided with all policies and procedures necessary to perform assessments for L-A-B. Updates to documents are available on the website and assessors are notified by email when new or revised documents are added to the website that directly affects their responsibilities.

B. ASSESSOR RECORDS

Assessor Records are maintained and contain:

a) Name and address
b) Organization affiliation and position held
c) Educational qualifications and professional status
d) Competence of people involved in accreditation process
e) Work experience
f) Training in quality assurance, assessment and calibration and testing
g) Experience in laboratory assessment, together with the field of competence
h) Date of most recent update of record
i) Signed Conflict of Interest and Impartiality Agreement
j) Assessor Evaluation Checklist

C. ASSESSOR MONITORING

Assessors are monitored to ensure the satisfactory performance of the assessment. This is done through on-site witnessing, feedback from clients, and technical evaluation reports.

6. ACCREDITATION PROCESS TO ISO/IEC 17025, SECTOR SPECIFIC AND L-A-B REQUIREMENTS

See SOP 205 "Accreditation Process" for details of operation.
All necessary documents and requirements can be found on the L-A-B website www.l-a-b.com.

A. APPLICATION FOR ACCREDITATION

The application information and Client Instruction Manual is available at www.l-a-b.com under the Process heading.

The laboratory must provide to L-A-B with Form 28 Application for Accreditation Quote, which contains the following information:

a) The general features of the applicant laboratory
    A) Name
    B) Address
    C) Legal status
    D) Human and technical resources
b) General information concerning the laboratory covered by the application
    E) Primary function
    F) Relationship in a larger corporate entity
    G) Physical locations of laboratories involved

H) Descriptions of services
I) List of standards

c) A definition, for the calibration to be assessed that consists of:
J) Type of measurement performed
K) Measurement range
L) Calibration and Measurement Capability
M) The limits of capability

d) A definition, for the tests to be assessed that consists of: (See appropriate Scope Preparation Matrix found on Website)
N) Materials or products tested
O) Methods used
P) Tests preformed

k) General Guidance is given to the laboratory referencing our guidance documents on the website: The Form 28 series is referenced for scope guidance and within those documents the Guidance for Documenting and Implementing ISO/IEC 17025 is referenced.

B. APPLICATION REVIEW

The accreditation body reviews its ability to carry out the assessment of the applicant laboratory in terms of its own policy, its competence, its ability to perform in a timely manner, and the availability of suitable assessors and experts.

After reviewing the application, a preliminary visit may be suggested with the agreement of the laboratory. This visit occurs before the assessment and may result in identification of deficiencies in system of the applicant laboratory or its competencies. L-A-B establishes clear rules and exercises due care to avoid consultancy during such activities. (SOP 205)

C. ASSESSMENT SUMMARY

Laboratory Assessors and lead assessors are assigned based on their qualifications and technical competence in the testing/calibration or types of testing/calibration to be assessed. The name(s) of the assessor(s) are to be promptly supplied to the laboratory. The laboratory has the right to ask for another assessor if they object to the original assignment, whereupon LAB shall review the objection (see SOP 205). L-A-B sends the lead assessor a copy of the laboratory's proposed Scope of Accreditation and an allocation that includes the number of man-days estimated to do the assessment.

The laboratory must complete the applicable checklist based on ISO/IEC 17025 with additional L-A-B requirements where relevant. The checklist along with the supporting documentation (ie. Quality Manual), is required to be submitted to L-A-B, prior to the tentatively scheduled assessment. Failure to submit these documents in a timely manner may delay the review. The assessment will be scheduled at a mutually agreed time with the assessors and the laboratory. For initial assessments, in addition to visiting the main or head office, visits will be made to all other premises of the laboratory from which one or more key activities are performed and which are covered by the scope of accreditation during the course of the accreditation. During this time, the assessment team should witness the performance of a representative number of the laboratory staff to assist in providing assurance, reliability, and understanding of the competence of the laboratory across the scope of accreditation.

The Lead Assessor or designee reviews the laboratory's documented quality system for compliance. The results of this review are documented on the appropriate checklist and this

serves as part of the technical package submittal. A report may be prepared that specifies where the laboratory's documented quality system is noncompliant.

1. The lead assessor, with the aid of the assessment team, is required to prepare an agenda. The agenda shall be forwarded to the laboratory prior to the assessment visit so that the laboratory can assure that the appropriate personnel are available when needed.

D. ASSESSMENT DOCUMENTATION

The assessment team will review all relevant documents and records supplied by the laboratory to help evaluate its system for conformity with the relevant standard(s) and other requirements for accreditation. Any nonconformity should be recorded and reported in writing to the laboratory. This procedure and its forms assure that L-A-B receives the necessary documentation to declare the competence of a laboratory when making a decision whether to accredit a laboratory or not. L-A-B has the right to cancel an on-site assessment based on the nonconformities found during this document review.

E. OPENING MEETING

This meeting will introduce the assessors to the management of the laboratory and define the scope of the work to be performed. It will also confirm the proposed agenda, schedule, and allow for adjustments.

F. ANALYSIS OF FINDINGS

The assessment team analyzes all relevant information and evidence gathered during the document and record review and the on-site assessment. This analysis should be sufficient to determine the extent of competency and conformity of the laboratory with the requirements for accreditation. The accreditation body will remain responsible for the content of the assessment report, including nonconformities. If the assessment team cannot reach a conclusion about a finding, the team should refer back to L-A-B for clarification.

G. CLOSING MEETING MINUTES

This meeting is conducted at the completion of the assessment, prior to the team leaving the laboratory. The meeting will include the assessors and the laboratory management. The assessors are required to present their assessment findings, both positive findings and noncompliance's. A copy of noncompliance (Form 33), assessment summary (Form 14) and approved Proposed Scope of Accreditation are presented to the laboratory. The laboratory will be afforded the opportunity to refute any of the noncompliances. The accreditation body must ensure that the responses of the laboratory to resolve nonconformities are reviewed to see if the actions appear to be sufficient and effective. If the laboratory responses are found to be insufficient, further information will be requested. Additionally, evidence of effective implementation of actions taken may be requested, or a follow-up assessment may be carried out to verify effective implementation of corrective actions.

H. ASSESSMENT REPORT

The client has 30 or 60 days to respond to the noncompliances noted during the assessment. Additional time may be afforded upon laboratory request. The client will use their own corrective

actions procedure to answer the noncompliances. The response, and all supporting documentation used as proof of implementation, must be forwarded to the L-A-B.

I. ACCREDITATION ANALYSIS

The information provided to the accreditation decision-maker(s) include, but are not limited to the following:

1) Unique identification of the laboratory
2) Date(s) of the on-site assessment
3) Name(s) of the assessor(s) and/or experts involved in the assessment
4) Unique identification of all premises assessed
5) Proposed scope of accreditation that was assessed
6) The assessment report
7) A statement on the adequacy of the internal organization and procedures adopted by the laboratory to give confidence in its competence, as determined through its fulfillment of the requirements for accreditation
8) Information on the resolution of all nonconformities
9) Any further information that may assist in determining fulfillment of requirements and the competence of the laboratory
10) Where applicable, a summary of the results of proficiency testing or other comparisons conducted by the laboratory and any actions taken as a consequence of the results
11) Where appropriate, a recommendation as to granting, reducing or extending accreditation for the proposed scope.

J. GRANTING ACCREDITATION

Each laboratory that is granted accreditation is issued a Certificate of Accreditation and a signed copy of their Scope of Accreditation. The Scope of Accreditation includes:

1. The calibrations or tests, or types of calibration or test, for which accreditation has been granted
2. For calibration, the type of measurement performed, the measurement range and Calibration and Measurement Capability
3. For test, the materials or products tested, the methods used and the tests performed
4. For specific calibrations and tests for which accreditation has been granted, the methods used, defined by written standards or reference documents that have been accepted by L-A-B
5. A statement of conformity and a reference to the standard(s) or other normative document(s), including issue or revision used for assessment of the laboratory
6. The effective date of accreditation, and the term of the accreditation
7. Unique number of the accredited laboratory
8. The identity and logo of L-A-B.

The Managing Director of L-A-B shall sign each Certificate and Scope of Accreditation.

The scope may also include the any of the following applicable items:

a) For calibration and dimensional measurement laboratories
   a. The calibrations, including the types of measurements performed, the measurement ranges and the Calibration and Measurement Capability (CMC) or equivalent

b) For testing laboratories
   a. The tests or types of tests performed and materials or products tested and where appropriate, the methods used.

K. ASSIGNMENT OF ASSESSORS FOR AFFILIATE PROGRAM

The responsibility for granting or denying of accreditation is solely the responsibility of L-A-B. The affiliates must follow the policies and procedures of L-A-B. The assessors are trained and qualified per this manual and are assigned by L-A-B.

L. PAYMENTS TO ASSESSORS

All payments to Assessors are made by L-A-B, based on expense statements submitted by the assessor at the completion of the visit. Where the accreditation visit is made under the Affiliate program, the Affiliate is invoiced for fees and expenses, which are then paid to the assessor by L-A-B.

M. SUBCONTRACTING THE ASSESSMENT

Normally, L-A-B will carry out the accreditation assessment process. Currently L-A-B does not subcontract assessments.

7. GRANTING, MAINTAINING, EXTENDING, SUSPENDING, AND WITHDRAWING ACCREDITATION

A. GRANTING OR DENYING ACCREDITATION

Upon the completion of the assessment a technically competent person will review the accreditation documentation. The determination to accredit the laboratory will be made by L-A-B based on the evaluation of all relevant information received and the degree to which the laboratory complies with the specific L-A-B requirements.

If a laboratory is granted accreditation, L-A-B sends them a Certification of Accreditation along with an approved Scope of Accreditation.

If a laboratory is denied accreditation, L-A-B notifies the laboratory of the decision, and provides them with the reasons for denying accreditation. If the laboratory disagrees with the reasons given for denial, they may appeal to the Managing Director of L-A-B, who will initiate the Appeals Procedure as defined in this manual. Appeal actions must be initiated within 30 days of the notification to deny accreditation.

B. MAINTAINING ACCREDITATION

Accreditation is maintained by surveillance assessments annually for two years, the third year a full ISO/IEC 17025 assessment is performed, and satisfactory participation in the appropriate proficiency testing and interlaboratory comparison programs.

Based on surveillance findings, it is possible that any surveillance visit may warrant a full re-assessment. If noncompliances are such that the assessor believes that a systemic problem exists, they may recommend that a full re-assessment be performed. The Program Manager or designee will review the assessment findings, and determine the necessity of a full re-assessment and the timeframe in which the assessment will be performed.

Under contractual arrangement with Regulators and/or Specifiers and the accredited laboratory, L-A-B may alter the accreditation cycle to a sector specific required maintenance schedule. The requirements for the program will be detailed in the program requirements for the sector specific program.

C. EXTENDING OR EXPANDING THE SCOPE OF ACCREDITATION

There are several circumstances that might require the extension of an accreditation. The accreditation body will, in response to an application for an extension of the scope of an accreditation already granted, undertake the necessary activities to determine whether or not the extension may be granted. In each instance the appropriate Program Manager will review all available documentation, which includes but is not limited to proficiency testing results, complaint files, and previous assessments, to determine whether the laboratory's accreditation may be extended for a defined period of time.

If a laboratory wishes to expand its scope of accreditation to include additional tests or fields of testing/calibration, the laboratory must submit, in writing, a request for the proposed expansion. This includes a copy of the test/calibration methods for which expansion is requested. The appropriate Program Manager reviews the proposed expansion to determine what actions may be necessary to grant the expansion. The actions may include, but are not limited to, the following:

1. If the tests are similar to the ones that the laboratory is currently accredited to perform, the submitted information will be reviewed by the assessor who performed the most current assessment. Based on the assessor's recommendation, L-A-B will determine whether the laboratory can, in fact, be granted the expansion, or whether an additional visit is necessary.
2. If the laboratory has asked for an expansion into a completely new field of testing, or the test method is not similar to that for which the laboratory is currently accredited, an assessment visit will be scheduled. The assessment visit will be limited to the technical assessor(s) capable of assessing the testing under consideration. The assessment visit will normally include only those elements that are necessary to determine the laboratory's technical competence with regard to the proposed expansion. However, if the assessor(s), during the investigation for the expansion, uncover evidence that indicates a systemic problem, they may choose to follow the thread until they are assured that a larger problem does or does not exist.

D. DECREASING SCOPE OF ACCREDITATION

When a laboratory loses a key person without replacing them, or loses the use of equipment necessary to perform an accredited test without replacing it, or any other change that may affect the capability of the laboratory, the laboratory is required to notify L-A-B immediately. L-A-B will

determine a course of action based on the circumstances. In all instances the test(s) in question will be removed from the laboratory's scope of accreditation.

Other actions may be necessary if the laboratory wishes to have the removed test method added to their scope of accreditation at a later date. These actions may include reassessment, review of test methods and documentation, and/or review of personnel qualifications.

E. COMPLAINTS RECEIVED ABOUT ACCREDITED LABORATORIES

When a complaint is filed against an accredited laboratory, the Quality Manager will determine if the complainant has contacted the laboratory to seek resolution. If resolution is not possible with the laboratory, the Quality Manager will initiate an investigation into the matter. If the investigation or any other matter indicates that a laboratory no longer complies with the requirements of this program, L-A-B shall initiate an immediate surveillance assessment.

F. TRANSFER OF ACCREDITATION

If the legal status (e.g. ownership) of an accredited laboratory changes, the information on the changes that have taken place shall be forwarded to L-A-B for review. The Program Manager, Director, Customer Service or their designee(s) will determine what actions may be necessary to continue the accreditation. These actions may include, but are not limited to the following:

1. Review and approval of changes, with no surveillance.
2. The review indicates that the changes could have an effect on the testing or calibrations; therefore, a surveillance visit is necessary immediately.
3. The review indicates that the changes can be covered at the next scheduled surveillance visit.

G. WITHDRAWAL OR SUSPENSION OF ACCREDITATION

The accreditation body will make decisions to suspend and/or withdraw accreditation when an accredited laboratory has persistently failed to meet the requirements of accreditation or to abide by the rules for accreditation. The accreditation body makes decisions to suspend and/or withdraw accreditation when an accredited laboratory has persistently failed to meet the requirements of accreditation or to abide by the rules for accreditation. The scope of accreditation of the laboratory can be reduced to exclude those parts where the laboratory has persistently failed to meet the requirements for accreditation, including competence. In the event that L-A-B proposes to withdraw or suspend accreditation, the laboratory will be notified of the reasons for such actions. The laboratory is given the opportunity to provide evidence that the reasons for withdrawal or suspension are not warranted. If the laboratory disagrees with the reasons, they may appeal to the Managing Director of L-A-B, who will initiate the Appeals Procedure SOP 203. Appeal actions must be initiated within 30 days of the notification to withdraw or suspend accreditation.

When an accreditation is withdrawn or suspended, the laboratory must cease using the L-A-B logo on its test and calibration reports and certificates in any way.

The laboratory must also return the Certificate of Accreditation and Approved Scopes of Accreditation.

H. ACCREDITATIONS OF LABORATORIES THAT HAVE BEEN DENIED, SUSPENDED OR WITHDRAWN

A laboratory who has been denied accreditation or had their accreditation suspended or withdrawn may apply for and be granted accreditation if the following requirements are met:

1. The laboratory management system must be in full compliance with ISO/IEC 17025 or relevant sector specific standard.
2. The laboratory can prove its technical competence in the tests or types of tests for which accreditation is sought.

I. DISPUTES AND APPEALS

A laboratory under evaluation may appeal an L-A-B decision not to grant, suspend, or withdraw accreditation see SOP 203. This appeal will be sent to L-A-B, in writing, within 30 days of notification of the decision of the Accreditation Committee. The appeal is required to state the reasons why the laboratory believes that the L-A-B decision was incorrect.

The Managing Director appoints a panel of three persons from the Technical Advisory Group to investigate the appeal. The selection process assures that the Appeals Panel members do not have a conflict of interest. All efforts will be made to assure that the panel members are acceptable to all parties concerned.

The panel will investigate the appeal and determine whether the appeal is justified or not. Based on the recommendation of the panel, L-A-B may decide to overturn the recommendation of the Technical Review Committee.

The accreditation body will take follow-up action where required. The records of all appeals, finals decisions, and follow-up actions will be kept and updated by L-A-B.

In the case of an appeal to a decision to suspend or withdraw accreditation, the accreditation will remain in effect during the appeal process.

8. PROFICIENCY TESTING

L-A-B requires all accredited laboratories to participate in proficiency testing or interlaboratory comparison programs PT/ILC for all fields that apply to their Scope of Accreditation (See Policy 002 Proficiency Testing). The laboratory must participate in one PT/ILC program prior to accreditation. In order to maintain their accreditation, every four years the laboratory must participate in one PT/ILC per major field for which they have been granted accreditation. The required programs will comply with ISO/IEC Guide 43 (ISO/IEC 17043). From time to time L-A-B may require the laboratory to participate in other interlaboratory comparisons (ILC).

The laboratory will authorize the PT/ILC provider to supply a copy of their report to L-A-B. The laboratory is required to provide L-A-B with the required information to allow monitoring of the laboratory's performance in the PT program.

Additional Proficiency Testing requirements may be required for accreditation programs required by sector specific requirements of regulators and/or specifiers. These requirements will be agreed by contract with the laboratory and may include a release from the laboratory to directly submit proficiency testing results to regulators and/or specifiers.

9. NOTIFICATION OF CHANGES

The laboratory is required to inform L-A-B immediately, as part of the Client Instruction Manual, of any changes in:

1. Legal, commercial or organizational status
2. Organization and management, e.g. key managerial staff

3. Policies or procedures that directly affect the validity of data
4. Physical location or premises
5. Key personnel, equipment, facilities, working environment or other resources that would impact the validity of data
6. Authorized signatories.

L-A-B must be notified of any other matters that may affect the laboratory's capability, scope of accredited activities, or compliance with the requirements for accreditation.

The laboratory will inform L-A-B of the actions that it has taken or will be taking to adjust its procedures, to ensure that the laboratory remains compliant with the requirements of accreditation.

L-A-B will inform its accredited laboratories of changes to the requirements for accreditation. L-A-B will inform the laboratory of the allotted time in which it must become compliant with the new requirements.

10. SURVEILLANCE AND REASSESSMENT OF ACCREDITED LABORATORIES

The plan for reassessment and surveillance of each accredited laboratory is such that representative samples of the scope of accreditation are assessed on a regular basis. Surveillance visits are conducted annually, and these surveillance visits will consist of 1/2 of all requirements of ISO/IEC 17025 or relevant standard, along with review of all corrective actions from the previous assessment/surveillance. Every three years a complete reassessment, which consists of all requirements, is performed on the accredited laboratories.

Surveillance visits may be scheduled more frequently should circumstances indicate that a laboratory is not compliant with the requirements of the L-A-B program. If a combination of reassessment and surveillance is relied upon, then L-A-B will undertake a reassessment at least every three years.

If during surveillance or reassessments nonconformities are identified, L-A-B will define strict time limits for corrective actions to be implements. A confirmation of the continuation of accreditation, or decision on the renewal of accreditation, based on the results or surveillance and reassessments will be conducted by L-A-B. Extraordinary assessments may be conducted as a result of complaints or changes. If this scenario occurs, the laboratory will be advised accordingly.

Under contractual arrangement with Regulators and/or Specifiers and the accredited laboratory, L-A-B may alter the accreditation cycle to a sector specific required maintenance schedule. The requirements for the program will be detailed in the program requirements for the sector specific program.

11. USE OF L-A-B LOGO AND SYMBOL

Accredited laboratories are granted the right to use the L-A-B symbol on the test report and calibration certificates, for those tests and calibrations where they have specifically been accredited. Tests that are not accredited must be identified as such when they appear in a report that has the L-A-B symbol on it. See Policy 012 for Control of Symbol for details.

12. RELATIONSHIP BETWEEN L-A-B AND LABORATORY

The laboratory will accommodate L-A-B during the accreditation process to assure that they are provided with the necessary materials, and appropriately arrange access to all areas of the laboratory necessary to assess the compliance of the laboratory. These accommodations extend to surveillance, reassessments and for purposes of resolving complaints against the laboratory.

An accredited laboratory will:

i. At all times comply with the provisions of the accreditation program, as defined in the document.
ii. Claim that it is accredited only for those services for which it has been granted accreditation and which are carried out in accordance with these conditions.
iii. Pays fees assessed by L-A-B.
iv. Not use its accreditation in a way that brings L-A-B into disrepute, and not make any statement relevant to its accreditation that L-A-B may consider misleading or unauthorized.
v. If the accreditation is suspended or withdrawn, laboratory will discontinue the use of all advertising materials that contain any reference to L-A-B, and return any certificate of accreditation to L-A-B.
vi. Not use its laboratory accreditation to imply product approval by L-A-B.
vii. Endeavor to ensure that no certificate or report, nor any part thereof is used in a misleading manner.
viii. Make sure that its references to their accredited status comply with the requirements of L-A-B in all communication media, such as advertising, brochures or other documents.
ix. Arrange the witnessing of laboratory services when requested by L-A-B.
x. Inform L-A-B, without delay, of matters that may affect the ability of the laboratory to fulfill requirements for accreditation.

L-A-B will:

i. Make the following information publicly available:
    1. Name and address of each accredited laboratory
    2. Current status of the accreditations it has granted.
ii. Update the information regularly with dates of granting accreditation and the dates of expiration, as applicable.
iii. Provide the laboratory with information about suitable ways to obtain traceability of measurement results in relation to the scope for which accreditation is provided.
iv. Provide information about international arrangements in which it is involved, where applicable.
v. Give due notice of any changes to its requirements for accreditation and verify that each accredited body carries out any necessary adjustments.

13. RELATIONSHIP BETWEEN L-A-B AND OTHER THIRD PARTIES

L-A-B may enter into arrangements with other third parties where coordination of accreditation by L-A-B and other third parties for their specific service.

14. DIRECTORY OF ACCREDITED LABORATORIES

L-A-B places the Scope of Accreditation of all laboratories on their website at www.L-A-B.com. This website is updated as needed.

15. NOTIFICATION OF CHANGE

L-A-B will notify all MRA partners and affected affiliates, within 30 days, of any changes:

a. In location, major changes in accreditation policy(s)
b. In key personnel
c. In name, legal or corporate status
d. To the scope of accreditations granted

L-A-B will also notify MRA partners and affected affiliates with details of:

a. Details of new agreements negotiated with of Abs, or other parties, and suspension or termination of any existing agreements (notification may be in the form of public release)
b. New programs conducted for regulatory agencies
c. Updates of other documentation shall be available upon request

Upon the decision of change, L-A-B notifies the affected parties on the amendments. The accreditation body verifies and documents that the laboratory executes the necessary adjustments.

16. RECORDS

Records on laboratories will include:

a) Relevant correspondence
b) Assessment records and reports
c) Records of committee deliberations and accreditation decisions, if applicable
d) Copies of accreditation certificates.

The accreditation body establishes procedures for retaining records for a period consistent with its contractual and legal obligations. Access to these records is consistent with the confidentiality arrangements. Records are filed in alphanumeric order by specific type of record. Records maintained are described in SOP 107. When records are transported, transmitted or transferred, they are handled in a manner to ensure that confidentiality is maintained. After the retention period has expired, all records are shredded to protect the confidentiality and proprietary rights of the client. Records are readily available on the property of L-A-B.

Sector specific requirements may further define sector specific requirements.

17. EXPANDING INTO NEW AREAS OF ACCREDITATION.

From time to time LAB may wish to expand into new areas of expertise (see SOP 111). The goal of the policy is to assure that the new program will assure that the laboratories accredited in the new area are technically competent, and adhere to the requirements of ISO/IEC 17025. The following steps will be followed to ensure that a sound technical program is developed.

To develop a new area L-A-B will do the following:

i. Assess the need for a program in the area under consideration.
ii. Assess the availability of the technical expertise needed to provide assessment of the laboratories.
iii. Enlist the services of Technical Experts in the field of testing or calibration being considered.
iv. Develop sector specific criteria for the program, if necessary.
v. Train assessors with the appropriate technical expertise for the level of knowledge for the area considered. Consideration is given to the following:

a. The types of laboratory services considered and the level of accuracy of the test or calibration (t/c).
b. The experience and education level of the assessors.

vi. Establish an Expert Committee for the area, if necessary, over and above the Technical Advisory Group.
vii. Ensure the documents are created by committees or persons possessing the necessary competence and adopt the essential documents and applications.
viii. Offer the services to all laboratories.

18. STATEMENT OF SERVICES PROVIDED

L-A-B currently offers laboratory accreditation to all laboratories, within the stated scope of services. (see Appendix A)

LAB offers public training course in Preparation for Accreditation and Assessor Training, for any laboratory or individual who wishes to take the training. LAB selects training personnel for use with policies and procedures defined in other quality system documentation.

19. GUIDELINES FOR ACCEPTING CONTRACTS

Training is provided for all laboratories and individuals who apply for the services. The service provided is a standard format training session that is provided for all clients. L-A-B does not consult with laboratories for purposes of preparing them for the accreditation process. All training offerings are of a standard format and general information is provided. Participation in such a training class is not mandatory for obtaining accreditation, nor does this training guarantee that the laboratory will be granted accreditation.

For the purposes of this document, consulting is defined as providing specific advice on the implementation of ISO/IEC 17025, for purposes of assuring that accreditation will be granted. This would consist of training developed specifically for the client laboratory.

20. RELATED DOCUMENTS

See SOP and Forms Index.

REVISION HISTORY

Revision Level	Revision Date	Revised By	Brief Description of Revision
Original Issue	5/18/00	Lynne Neumann	Original Issue
Rev. 1	10/10/00	Lynne Neumann	Applied revision information and approval, added notification of MRA partners & affiliates.
Rev. 2	11/27/00	Lynne Neumann	Updated the proficiency testing requirements to reflect current international practices. Added form and procedure references. Updated the reporting section to reflect current practices. Added scheduling items to assessment section.
Rev. 3	4/24/01	Lynne Neumann	Cleaned up some typos and references.

Rev. 4	7/31/01	Lynne Neumann	Clarified the responsibilities of the Program managers. Included references to 17025 where missed. Added numbering. Added expanding into new areas, Satellite offices, Statement of Services provided and Guidelines for accepting contracts.
Rev. 5	11/12/03	Lynne Neumann	Revised to reflect current organization structure.
Rev 6	02/28/04	Robert Levine	Minor editorial corrections
Rev 7	03/16/04	Doug Leonard	Further explanation of the TAG and Expert Committee Responsibilities and inserting Quality Manager responsibility for yearly review of the quality system.
Rev 8	04/26/04	Robert Levine	Includes Affiliate and other third party programs within the process
Rev 9	10/22/05	Linda Mumma	Update the Manual to ISO/IEC 17011 requirements and additional improvements
Rev 10	12/06/05	Jason Stine	Corrected section 17 and index to reference SOP 111.
Rev 11	03/30/06	Jason Stine	Changed address
Rev 12	05/30/06	Ryan Fischer	Generalized complaints, expanded Appendix A.
Rev 13	07/18/06	Doug Leonard	Additional Fields added to Appendix A
Rev 14	02/14/09	Doug Leonard	A full review of the manual taking into account sector specific requirements of regulators and specifiers
Rev 15	02/16/10	Randy Long/Doug Leonard	Effected change from BMC to CMC and updates to current SOP's and Policies
Rev 16	04/27/10	Doug Leonard	Delete Form 35 Reference
Rev 17	5/28/11	Linda Mumma	Address change
Rev 18	6/21/11	Randy Long	Terminology change from "Dimensional Inspection" to "Dimensional Measurement"

APPROVED: DATE: _____ **DATE: 6/21/11**

Appendix A

LABORATORY ACCREDITATION BUREAU (L-A-B)
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TESTING FIELDS

- Acoustical
- Biological
- Microbiology
- Chemical
- Construction Materials
- Electrical
- Energy Consumption
- Environmental
- Information Technology
- Mechanical
- Non-Destructive
- Vibration
- Optical & Radiation
- Thermal

CALIBRATION OR MEASURMENT FIELDS

- Accelerometry
- Acoustics
- Amount of Substance
- Electrical
- Fluid Properties and Quantities
- Ionizing Radiation
- Length
- Luminous Intensity
- Mass
- Thermodynamics
- Time and Frequency
- Dimensional Measurement (Dimensional Inspection)